

NCI Common Toxicity Criteria for adverse events

What is CTCAE?

A reference 'library' of definitions for grading the effects of cancer treatment.

Purpose:

- To facilitate the evaluation of new therapies, treatment modalities, and supportive measures
- To standardize reporting of Adverse Events across groups and modalities without regard to chronicity.

History

The NCI, USA first developed Common Toxicity Criteria (CTC) in 1982. The CTC were used to report adverse drug experiences, adverse event summaries, reports to FDA and scientific publications.

In 1998, the Cancer Therapeutics evaluation Program (part of NCI) released Common Toxicity Criteria version 2.0 (CTC v2.0). The criteria were revised as part of international harmonization efforts, and were reviewed by the CTC Review Committee, this committee involved representatives of major clinical trials groups in Canada, Europe, Japan & USA, pharmaceutical industry, the FDA, & the Committee for Proprietary Medicinal Products (CPMP). The CTC v2.0 has become the international standard for reporting acute adverse events in cancer clinical trials.

The Common Terminology Criteria for Adverse Events (CTCAE) was released in March 2003. This version includes a system for grading late adverse events and a more complete set of surgical AEs. The CTCAE is being incorporated into new clinical trials as they are developed and will become the new standard for reporting of adverse events in cancer clinical trials.

What are the differences?

There are only slight variations between the CTC v2.0 and the CTCAE. The objectives of the revision were to expand the core CTC criteria to include adverse events applicable to all oncology clinical trials regardless of chronicity or modality.

The CTCAE includes a contents page to facilitate classification and grading of AEs. They also include navigation notes to prompt user to look at another category if need be.

A guideline mapping the CTCAE to the CTC v2.0 is available on the website.

<http://ctep.cancer.gov/reporting/ctc.html>